IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No: 62130-0009

Applicant(s):	Helen LEE et al.	Confirmation No.: 9058
App. No.:	10/500,167	Examiner: N. Archie
Filing Date:	October 12, 2004	Group Art Unit: 1645
Title:	SAMPLE PREPARATION FOR THE DETECTION OF INFECTIOUS AGENTS	

RESPONSE TO RESTRICTION REQUIREMENT

United States Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, VA 22314.

Sir:

In response to the Office Action issued on February 23, 2007 (Paper No. 20070214), applicants hereby elect with traverse Group I (claims 1-17) as set forth by the examiner for prosecution in the subject application. Applicants, of course, reserve the right to file one or more divisional applications covering the subject matter of the non-elected claims.

On pages 2-3 of the office action, the examiner alleges that the claims of Group I and II do not relate to a single general inventive concept because they lack the same or corresponding "special technical features". The examiner believes that the technical feature of Group I is anticipated by Biswas *et al.* (*Journal of Clinical Microbiology* 1997, 35:1560-1564). According to the examiner, Biswas teaches a method for treatment of a human patient sample (cervical brush smears) (refers to page 1560 paragraph 1-3) for carrying out a diagnostic method on the sample for detection of an infectious agent (HPV-16 E5) (refers to page 1567 "Results section"), wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying

out the diagnostic method in the presence of DNase (refers to page 1560, last paragraph to 1561, first paragraph).

Applicants respectfully disagree with the examiner and indicate that Biswas discloses detection of HPV-16 early gene transcription by RT-PCR. Biswas analyzed cervical brush smears obtained from patients and before carrying out RT-PCR, incubated the samples overnight with DNase-I. RNA was then extracted with phenol-chloroform-isoamyl alcohol prior to ethanol precipitation with linear polyacrylamide as a carrier. As would be apparent to the skilled person, DNase-I is removed from the RNA by this procedure. Consequently, the subsequent RT-PCR procedure disclosed in Biswas was not performed in the presence of DNase. Indeed, since RT-PCR involves the synthesis of DNA, it would be most undesirable for the RT-PCR procedure to be carried out in the presence of DNase. Therefore, there is no disclosure in Biswas *et al.* of carrying out a diagnostic method in the presence of DNase.

The Examiner also cites Tarkowski *et al.* (*Molecular Diagnosis,* 2001, vol. 6, no. 2, pgs. 125-130), although no specific disclosure in this document appears to be referred to by the Examiner. Again, applicants respectfully disagree with the examiner and point out that Tarkowski *et al.* disclosure relates to improved detection of viral RNA isolated from liquid-based cytology samples. Applicants explain that Tarkowski extracted the total nucleic acid (TNA) from cell lines grown in the laboratory (either from fresh cells or from cells fixed in liquid-based cytology media) and the extracted TNA was then treated with DNase-I to allow analysis of the RNA in the samples by RT-PCR. Although cervical cytology samples are referred to (page 125, first line, last paragraph; page 129, last paragraph), there is no disclosure of carrying out the procedure described on an endocervical fluid sample or a vaginal fluid sample. The last paragraph of page 129 makes it clear that optimization is required before initiating molecular diagnostics on clinical samples.

Applicants also point out that there is also no disclosure in Tarkowski *et al.* of carrying out a diagnostic method in the presence of DNase. The section headed "Reverse Transcription" on page 126, right column, states that DNA was removed from

TNA sample using DNase-I MessageClean kit. Five microgram glycogen was added immediately before the final ethanol precipitation, and DNase-I-treated RNA was re-suspended in DMPC-treated water. Again, DNase-I was removed by this procedure. Therefore, the subsequent procedure was not performed in the presence of DNase.

Applicants submit that the "special technical feature" shared by the subject matter of the claims of Group I and II, *inter alia*, is the step of carrying out the diagnostic method in the presence of DNase. This feature is not disclosed in either of the cited prior art documents. Accordingly, the invention listed as Groups I and II by the Examiner do relate to the same general inventive concept.

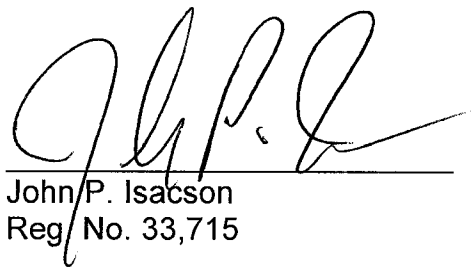
Applicants traverse the restriction requirement on the grounds related to the issue of "special technical features", as discussed above, and that the examiner has not demonstrated the requisite "serious burden" needed to justify a restriction requirement. See MPEP § 803(B) at 800-4. Thus, applicants submit that there would be no serious burden to examine all of the claims, including the claims of Group II (claims 18-22). Therefore, applicants request withdrawal of the restriction requirement and examination of all claims, including the claims of Group II (claims 18-22).

Applicant petitions for a two-month extension of time, as well as any other needed extension, and provides the requisite fee herewith. Please debit any underpayments, or credit any overpayments, to firm deposit account no. 50-3840.

A first office action on the merits is awaited. It is respectfully submitted that the application is in condition for examination, and an early action on the merits is courteously requested.

The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



May 3, 2007
Date

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